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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EPPERSON, JON D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary <i>File Copy</i>	Application No.	Applicant(s)	
	09/738,871	SHORT ET AL.	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- ~~Th~~ MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is (703) 308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner, at (703) 306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-18 and 21-42 and 45-60, 61 (in part, i.e., steps (a)-(c) in claim 61 would not be included), 62-64 drawn to a method for "identifying a bioactivity or a biomolecule of interest", classified variously in class 435, subclass 4, 6, 7.1, DIG 15, DIG 17.
 - II. Claims 19-20 and 43-44, 61 (in part, i.e., steps (d)-(e) in claim 61 would not be included) drawn to a method for "generating a polynucleotide library", classified variously in class 435, subclass 6, DIG 46, DIG 47.
 - III. Claims 65-72, drawn to a method for "obtaining an organism from a mixed population of organisms", classified variously in class 435, subclass 30, DIG 5.
2. The inventions are distinct, each from the other because of the following reasons:

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3. The methods of Groups I-III are patentably distinct because they use different steps, require different reagents and/or will produce different results. Group I represents a method for “screening” for a biomolecule of interest, whereas Group II is a method for “producing” a library and Group III is a method for selecting microorganisms. Therefore, searching Groups I-III together would represent an undue search burden because divergent patent and non-patent literature searches would be required. Furthermore, the inventions can be separately classified (see paragraph 1 above). In addition, art anticipating or rendering obvious each Group i.e., Groups I-III would not render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group will support separate patents. Therefore, Groups I-III have different issues regarding patentability and enablement and represent patentably distinct subject matter.

4. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

5. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-III. Please Note: applicant must elect *one* species from *each* subgroup below. Election is required as follows:

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6. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of bioactivity (see claim 1)

Applicant must elect, for the purposes of search, a single species of bioactivity e.g., ligase (see specification, paragraph 125). Please do not elect a “broad” species like “enzyme activity” that would include “more than one” bioactivity because a “single species” is required for election.

Subgroup 2: Species of biomolecule (see claim 1)

Applicant must elect, for the purposes of search, a single species of biomolecule e.g., daunomycin (see specification, paragraph 12). Please do not elect a “broad” species like “polyketides” that would include “more than one” bioactivity because a “single species” is required for election (see specification, paragraph 88 outlining the various members that are contained within the broad “polyketide” classification).

Subgroup 3: Species of organisms (see claim 1)

Applicant must elect, for the purposes of search, a single species of organism e.g., psychrotrophs (see claim 69). If applicant objects to picking a “single species” from a “mixed” population of organism, applicant is still required to pick a “representative example” of organism. Please do not elect a “broad” species like “microorganism” that would include “more than one” organism because a “single species” is required for election. Applicants must further indicate where the organism was derived from e.g., the environment.

Subgroup 4: Species of detectable molecule (see claim 1)

Applicant must elect, for the purposes of search, a single species of detectable molecule wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the detectable molecule. Applicant should not use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected.

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Subgroup 5: Species of library (see claim 1)

Applicant must elect, for the purposes of search, a single species of library e.g., λ -ZAP II library (see Example 5 in specification). Applicant must not elect a broad category of libraries i.e., “expression library” as more than one species of library would be erroneously elected.

Subgroup 6: Species of detectable molecule properties (see claims 1, 4-6)

Applicant must elect, for the purposes of search, a single species of detectable molecule properties e.g., fluorescent, magnetic.

Subgroup 7: Species of analyzer (see claim 5)

Applicant must elect, for the purposes of search, a single species of analyzer e.g., FACS analyzer (see claim 8). Applicant must not elect a broad category of analyzers like “magnetic field sensing device” because more than one species of analyzer would be erroneously elected.

Subgroup 8: Species of reporter system (e.g., see claim 2)

Applicant must elect, for the purposes of search, a single species of reporter system e.g., C12FDG with lipophilic tail (see claims 16 and 17). Applicants must further set forth a specific structure, which clearly shows all of the atoms and bonds that are necessary to define the reporter system e.g., must show all atoms and bonds of C12FDG with lipophilic tail including any connecting atoms and bonds. Applicant should not use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. Applicant must not elect a broad category of reporter systems like “bioactive substrate” or “detectable label” or “comprises a first test protein” because more than one species would be erroneously elected as the broad categories comprise more than just one single species. Applicants must also indicate what activity (if any) the reporter system has.

Subgroup 9: Species of encapsulation (see claim 21)

Applicants must first indicate whether or not the clones are encapsulated e.g., yes or no. If yes, applicant must elect, for the purposes of search, a single species of encapsulation e.g., ghost red blood cells (see claim 22). Applicant must not elect a broad category of

encapsulation like “microenvironment” because more than one species of analyzer would be erroneously elected.

Subgroup 10: Species of polynucleotide of interest (see claims 24-25)

Applicant must elect, for the purposes of search, a single species of polynucleotide of interest e.g., lignin peroxidases (see claim 25). Applicant must not elect a broad category of polynucleotide of interest like “enzyme” or “operon encoding a complete or partial metabolic pathway” because more than one species of polynucleotide of interest would be erroneously elected e.g., a single species polynucleotide of interest must be elected.

Subgroup 11: Species of oligonucleotide probes heterogeneity (see claim 1)

Applicant must elect, for the purposes of search, a single species of oligonucleotide probe heterogeneity e.g., must pick “same sequence” or “different sequence” (see claim 60).

7. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 19 is generic.

Subgroup 1: Species of organism (see claim 19)

Applicant must elect, for the purposes of search, a single species of organism e.g., psychrotrophs (see claim 69). If applicant objects to picking a “single species” from a “mixed” population of organism, applicant is still required to pick a “representative example” of organism. Please do not elect a “broad” species like “microorganism” that would include “more than one” organism because a “single species” is required for election. Applicants must further indicate where the organism was derived from e.g., the environment.

Subgroup 2: Species of obtaining polynucleotides from a mixed population of organism (see claim 19)

Applicant must elect, for the purposes of search, a single species of obtaining polynucleotides from a mixed population of organism. Please note that electing a “broad category” that contains more than one species will result in a non-compliance letter.

Subgroup 3: Species of library (see claim 19)

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Applicant must elect, for the purposes of search, a single species of library e.g., λ -ZAP II library (see Example 5 in specification). Applicant must not elect a broad category of libraries i.e., “expression library” as more than one species of library would be erroneously elected. Please note that electing a “broad category” that contains more than one species will result in a non-compliance letter.

Subgroup 4: Species of generating a polynucleotide library (see claim 19)

Applicant must elect, for the purposes of search, a single species of generating a polynucleotide library. Please note that electing a “broad category” that contains more than one species will result in a non-compliance letter.

8. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 65 is generic.

Subgroup 1: Species of organisms (see claim 65)

Applicant must elect, for the purposes of search, a single species of organism e.g., psychrotrophs (see claim 69). If applicant objects to picking a “single species” from a “mixed” population of organism, applicant is still required to pick a “representative example” of organism. Please do not elect a “broad” species like “microorganism” that would include “more than one” organism because a “single species” is required for election. Applicants must further indicate where the organism was derived from e.g., the environment.

Subgroup 2: Species of encapsulation (see claim 21)

Applicants must first indicate whether or not the clones are encapsulated e.g., yes or no. If yes, applicant must elect, for the purposes of search, a single species of encapsulation e.g., ghost red blood cells (see claim 22). Applicant must not elect a broad category of encapsulation like “microenvironment” because more than one species of analyzer would be erroneously elected.

Subgroup 3: Species of flow cytometer (see claim 65)

Applicant must elect, for the purposes of search, a single species of flow cytometer e.g., SQID (see claim 71). Please do not elect a “broad” species like “magnetic field sensing

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device” that would include “more than one” bioactivity because a “single species” is required for election.

9. **PLEASE NOTE:** applicant **MUST** indicate which claims read on the elected species above otherwise applicant will be held **nonresponsive** (see paragraphs 12-13 below).

10. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Applicant is advised that a reply to this requirement **must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered **nonresponsive** unless accompanied by an election.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. **If claims are added after the election, applicant must indicate which are readable upon the elected species.** MPEP § 809.02(a).

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

16. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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17. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an “action on the merits” for purposes of the second action final program, see MPEP 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
February 9, 2003

BENNETT CELSA
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'Bennett Celsa', written over the printed name and title.

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